

Medical Imaging Drugs Advisory Committee Meeting
June 28-29, 1999
Food and Drug Administration
Center for Drug Evaluation and Research

Holiday Inn, The Ballrooms, Two Montgomery Village Avenue, Gaithersburg, Maryland

June 28, 1999

8 a.m.

Welcome

Ruth G. Ramsey, M.D., MIDAC Chair

Patricia Love, M.D., M.B.A.

Director, Division of Medical Imaging and Radiopharmaceutical Drug Products, CDER - FDA

Meeting Announcements & Conflict of Interest Statement --

Leander B. Madoo, Executive Secretary for MIDAC, CDER - FDA

8:30-9:30

Open Public Hearing (One hour is allocated for all presentations and for Committee Questions on the presentations. The next agenda item will begin immediately if less than one hour is needed.)

9:30-10:00

Section 121 of the FDA Modernization Act on PET and proposed regulatory approach to three PET Drugs - Fludeoxyglucose F 18 Injection, Ammonia N 13 Injection, and Water O 15 Injection.

Jane Axelrad, Esq.

Associate Director for Policy

Center for Drug Evaluation and Research (CDER) - FDA

10:00-10:15 -

Committee Discussion / Questions

10:15-10:30

Break

10:30-11:30	<p>FDA Presentation on the Safety and Effectiveness of Fludeoxyglucose F 18 Injection</p> <p>Clinical Pharmacology/Pharmacology/Toxicology <i>FDA Speaker</i></p> <p>Safety and Effectiveness in Oncology <i>Florence Houn, M.D., M.P.H.</i> <i>Director, Office of Drug Evaluation III</i></p>
11:30-12:30	<p>Safety and Effectiveness in Cardiology <i>Victor F.C. Raczkowski, M.D., M.S.</i> <i>Deputy Director, Office of Drug Evaluation III</i></p>
12:30-1:30 pm	<p>Lunch</p>
1:30-1:45	<p>Open Public Comments on FDA's Presentation</p>
1:45-2:30	<p>Committee Discussion on FDA's Presentation</p>
2:30-2:45	<p>Break</p>
2:45-3:45	<p>FDA Presentation on the Safety and Effectiveness of Ammonia N 13 Injection</p> <p>Clinical Pharmacology/Pharmacology/Toxicology <i>FDA Speaker</i></p> <p>Safety and effectiveness in Cardiology <i>Florence Houn, M.D., M.P.H.</i></p>
3:45-4:00	<p>Open Public Comments on FDA's Presentation</p>
4:00-4:45	<p>Committee Discussion on FDA's Presentation</p>
5:00p.m.	<p>Adjournment for First Day</p>

June 29, 1999

8:00-9:00	Overview
9:00-10:00	FDA Presentation on the Safety and Effectiveness of Water O 15 Injection in Neurology Clinical Pharmacology/Pharmacology/Toxicology <i>FDA Speaker</i> Safety and effectiveness in Neurology <i>Patricia Y. Love, M.D., M.B.A.</i>
10:15-10:30	Open Public Comments on FDA's Presentation
10:30-10:45	Break
10:45-11:30	Committee Discussion on FDA's Presentation
11:30-12:30	Lunch
12:30-2:30	Open Public Hearing (if needed)
2:30-2:45	Break
2:45-4:00	Open Public Hearing (if needed)
5:00 p.m.	Adjournment